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Limited  
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Mayne Pharma International Pty. Ltd

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Attorneys for Plaintiffs  
Warner Chilcott Laboratories Ireland Limited  
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Warner Chilcott (US), LLC

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

-----X  
:  
WARNER CHILCOTT LABORATORIES :  
IRELAND LIMITED, :  
WARNER CHILCOTT COMPANY, LLC, :  
WARNER CHILCOTT (US), LLC and :  
MAYNE PHARMA :  
INTERNATIONAL PTY. LTD., :  
:  
Plaintiffs, :  
:  
v. :  
:  
MYLAN PHARMACEUTICALS INC. :  
and MYLAN INC., :  
:  
Defendants. :  
-----X

**Civil Action No.: 2:09-cv-2073-WJM-MF**  
(Consolidated with 2:08-cv-6304-WJM-MF, 2:09-cv-228-WJM-MF, 2:09-cv-469-WJM-MF, and 2:09-cv-01233-WJM-MF for discovery purposes)

**PLAINTIFFS' REPLY TO THE MYLAN DEFENDANTS' COUNTERCLAIM**

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, LLC, and Warner Chilcott (US), LLC, and Mayne Pharma International Pty. Ltd. (collectively "Plaintiffs") reply to the Counterclaim of Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively "Mylan") as follows:

**COUNTERCLAIM**

For its counterclaim against Plaintiffs, Mylan avers as follows:

**Answer:** This introductory statement does not require a response. To the extent that a response is required, admitted.

1. This is a counterclaim for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 for the purpose of determining an actual and justiciable controversy between the parties. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

**Answer:** Admitted

**CLAIM FOR RELIEF**

2. Plaintiffs brought an action against Mylan for alleged infringement of the '161 patent, based on the submission of ANDA No. 91-052 by Mylan Pharmaceuticals Inc.

**Answer:** Admitted.

3. The claims of the '161 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation, one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

**Answer:** Denied.

4. Mylan has not directly or indirectly infringed any valid claims of the '161 patent.

**Answer:** Denied.

5. The manufacture, use, offer for sale, sale, and/or importation of the drug product that is the subject of ANDA No. 91-052 would not infringe any valid claims of the '161 patent.

**Answer:** Denied.

6. A definite and concrete, real and substantial, justiciable controversy exists between the parties regarding, *inter alia*, the invalidity and non-infringement of the '161 patent, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

**Answer:** Admitted that there is a justiciable controversy between Plaintiffs and Mylan regarding the alleged non-infringement of the '161 patent. Denied in all other respects.

#### **PRAYER FOR RELIEF**

7. The "WHEREFORE" paragraph following paragraph 6 of the Counterclaim and the six lettered paragraphs (A-F) that follow it state the Mylan Defendants' prayer for relief, to which no response is required. To the extent that a response is required, Plaintiffs deny the allegations set forth in the "WHEREFORE" paragraph following paragraph 6 of the Counterclaim and the six lettered paragraphs (A-F) that follow it and deny that the Mylan Defendants are entitled to any of the relief requested therein, or to any relief whatsoever.

8. Plaintiffs deny any and all allegations of the Counterclaim not expressly admitted herein.

Respectfully Submitted,

Dated: June 16, 2009

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that true copies of the foregoing papers were caused to be served on June 16, 2009 via ECF and/or email upon the following counsel for Defendants

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